



Medtronic

AneuRx AAAAdvantage Stent Graft System

Product Features & Specifications

Surgical

Clinical

References

Patient

Indications

Contraindications

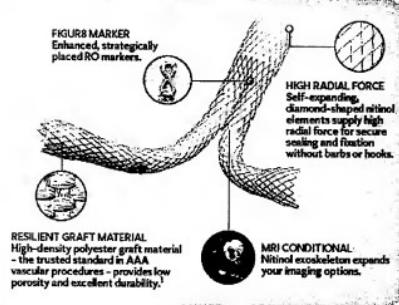
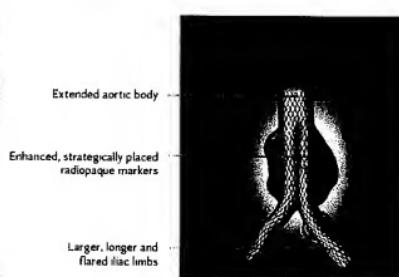
Warnings

Precautions

Adverse Events

AneuRx AAAAdvantage Stent Graft System

The **AAAAdvantage stent graft** is designed to offer longer fixation zones, enhanced control and more options.



EXPERIENCE CONTROL OPTIONS

References

1. Data on file at Medtronic, Inc.

Additional Information

- [Contact Medtronic Vascular](#)
- [aneurxaaaadvantage.com](#)



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Monday, March 5, 2007

Talent™ Thoracic Stent Graft System

Cardiac Surgery Vascular Surgery

Medtronic, Inc. has just submitted the final pre-market approval documents to the FDA for its Talent™ Thoracic Stent Graft System. At the present time there is no evidence to expect that the FDA would create any hurdles for the company to commercially market and sell its endovascular system for descending thoracic aneurysms.

From the press release:

Minimally invasive therapies, such as endovascular stent grafting, provide potential benefits including reduced surgical morbidity, reduced hospital stay, and an improved quality of life. The procedure involves threading the stent graft through a small opening in the femoral artery of the leg. The stent graft is advanced under fluoroscopic guidance to the site of the thoracic aortic aneurysm, where it is then positioned and deployed from the delivery system. Once deployed, the stent graft expands to fit snugly within the diameter of the aorta, providing a new path for the blood flow.

Medtronic has been at the forefront of the endovascular stent graft industry, with more clinical research and product implants than any other company. Its long history includes more than 100,000 patients treated with aortic stent grafts dating back to 1996. In addition to the Talent Thoracic stent graft, the company also markets the Valiant Thoracic Stent Graft System outside the United States. Medtronic also offers two stent grafts for abdominal aortic aneurysms (AAA): the Talent Abdominal Stent Graft system outside the U.S. and the popular AneuRx® AAAAdvantage Abdominal Stent Graft system in the U.S.

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New Device Approval

FLAIR Endovascular Stent Graft - P060002



This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness Data (SSED) and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: FLAIR Endovascular Stent Graft

PMA Applicant: Bard Peripheral Vascular

Address: 1625 West 3rd Street, Tempe, AZ 85280-1740

Approval Date: July 23, 2007

Approval Letter: <http://www.fda.gov/cdrh/pdfs/p060002a.pdf>

What is it? The FLAIR Endovascular Stent Graft is used to treat a stenosis, a narrowing or blockage, which has developed at the connection of a vein and an arteriovenous (A-V) access graft, known as the venous anastomosis. An A-V access graft acts as an artificial blood vessel that can be used repeatedly to draw blood with a needle during hemodialysis. The FLAIR Endovascular Stent Graft is a flexible, self-expanding tube made of ePTFE (expanded polytetrafluoroethylene) and a metallic support structure known as a stent, which holds the device open within the vein and A-V access graft. The stent graft is compressed into the end of a long, thin, tube-like device called a delivery catheter so that it can be implanted in the body.

The FLAIR Endovascular Stent Graft is the first endovascular system approved to treat a stenosis at the venous anastomoses of an A-V access graft.

How does it work? The FLAIR Endovascular Stent Graft is used after balloon inflation is performed to open the narrowed segment in the A-V access graft. The delivery catheter containing the endovascular graft is inserted into the A-V access graft and placed across the narrowed segment that has just been opened with the balloon. The endovascular graft is then released and self-expands so that it is pressing against the A-V access graft and blood vessel to keep the area open.

When is it used? The FLAIR Endovascular Stent Graft can be used to support or hold open a narrowed